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ANDRUS, SCEALES, STARKE & SAWALL, LLP
Suite 1100
100 East Wisconsin Avenue
Milwaukee, WI 53202

EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

1
2
3 RECORD OF ORAL HEARING
4 UNITED STATES PATENT AND TRADEMARK OFFICE
5
6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

9 Ex parte STEPHEN A. JOHNSTON, KATHERINE STEMKE-HALE,
10 KATHRYN F. SYKES, and BERNHARD KALTENBOECK
11

12 Appeal 2009-006341
13 Application 10/023,437
14 Technology Center 1600
15

16 Oral Hearing Held: January 14, 2010
17
18
19

20 Before TONI R. SCHEINER, DEMETRA J. MILLS, and
21 FRANCISCO C. PRATS, Administrative Patent Judges
22

23 ON BEHALF OF THE APPELLANTS:
24

25 M. SCOTT MCBRIDE, ESQ.
26 Andrus, Sceales, Starke and Sawall, LLP
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1 The above-entitled matter came on for hearing on Thursday,
2 January 14, 2010, commencing at 9:46 a.m., at the U.S. Patent and
3 Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Kevin E.
4 Carr, Notary Public.

5 THE USHER: Calendar number 47, Appeal number
6 2009-006341.

7 Mr. McBride.

8 JUDGE SCHEINER: Thank you. Good morning. We're all
9 anxious to hear how this organism is -- this species name is pronounced.

10 MR. MCBRIDE: Chlamydia psittaci.

11 JUDGE SCHEINER: Psittaci, okay.

12 MR. MCBRIDE: Or psittaci, or psittaci.

13 JUDGE SCHEINER: All right. Well, we all guessed wrong.

14 MR. MCBRIDE: Well, you know, actually, I had to look it up
15 on the internet, actually had the pronunciation --

16 JUDGE SCHEINER: Oh, okay.

17 MR. MCBRIDE: I prepared some benchbook materials. I
18 don't -- that might help.

19 JUDGE SCHEINER: Are these things that are already in the
20 record?

21 MR. MCBRIDE: They're already in the record.

22 JUDGE SCHEINER: Okay. That's fine then, but we'll hand
23 them back to you when we're done.

24 MR. MCBRIDE: Okay, that's fine. Let me just --

25 JUDGE SCHEINER: We're not going to enter them into the
26 file. Okay, thank you.

1 JUDGE PRATS: Thank you.

2 JUDGE SCHEINER: We do actually have everything up here
3 on our screens, so --

4 MR. MCBRIDE: Oh, okay. Okay, good. And you have to
5 excuse my -- I'm a novice at this.

6 JUDGE PRATS: That's okay. Yeah, basically what we're --

7 THE REPORTER: I need you to be by the podium.

8 MR. MCBRIDE: Oh, okay. All right.

9 THE REPORTER: It's for the microphone.

10 MR. MCBRIDE: Oh, thank you.

11 JUDGE SCHEINER: Okay. Well, whenever you're ready,
12 we're ready.

13 MR. MCBRIDE: Okay. Well, the question that the Appellants
14 have asked the Board to address is whether or not the specification provides
15 enablement for a method of immunizing an animal in an effective -- amount
16 effective to induce an immune response against chlamydia psittaci, wherein
17 the chlamydia psittaci antigen comprises the amino acid or polypeptide
18 sequences as set forth in sequence ID number 7. There's also further
19 dependent claims where additional antigens are administered in the
20 immunization method.

21 The Office's position is that while the specification is enabled
22 for a method of immunizing an animal in amount effective to induce an
23 immune response against chlamydia psittaci wherein the chlamydia psittaci
24 antigen comprises a mixture of antigens, the specification is not enabled for
25 a method of administering a single antigen.

1 JUDGE SCHEINER: Can I interrupt you right here, please?
2 Those -- these antigens represented by seq ID number 7, 9, 13, how are they
3 related? Are they overlapping parts of the same protein? Are they different
4 proteins from this organism or --

5 MR. MCBRIDE: They're overlapping. Initially all of these
6 antigens were identified as fragments using a method called expression
7 library immunization.

8 JUDGE SCHEINER: Mm-hmm, sure.

9 MR. MCBRIDE: So basically they identified various
10 fragments and they were given original sequence ID numbers. Subsequently
11 those fragments were compared to the completed genome of chlamydia
12 pneumoniae, and then the full length genes were identified. And those
13 were -- those sequence ID numbers were also presented. So for instance,
14 sequence ID number 7 is the originally identified fragment using the
15 expression library immunization.

16 JUDGE SCHEINER: Okay.

17 MR. MCBRIDE: Sequence ID number 9 is the full length gene
18 that encompasses that fragment.

19 JUDGE SCHEINER: Okay. So 7 is embedded in 9 then.

20 MR. MCBRIDE: Exactly.

21 JUDGE SCHEINER: Okay.

22 MR. MCBRIDE: Right. And the same thing for the
23 polynucleotide 6 and 8. And so if you look at table 3 it correlates all the
24 different fragments.

25 JUDGE SCHEINER: Okay, okay. Thank you.

1 JUDGE MILLS: Your claims are only intended to cover the
2 amino acids? They're not -- they do not cover the nucleic acids --

3 MR. MCBRIDE: That's correct. That's correct. And that's one
4 of the issues that I think is -- that needs to be addressed as well. The Office
5 has raised that issue, that our -- we're claiming a method of administering an
6 antigen. We have examples where we've administered DNA. We do have
7 examples where we've administered a mixture of the antigens, but they
8 would like you to decide whether or not we're enabled for a method of
9 administering a single antigen in view of that.

10 JUDGE MILLS: Okay.

11 MR. MCBRIDE: So we have several examples in the
12 specification. One example -- well, let me back up. Initially 14 clones -- of
13 all the clones that were synthesized in the library, 14 clones were narrowed
14 down. Those were administered individually as DNA in a mouse model, a
15 mouse -- what they call the lung weight increase model. They correlated
16 that lung weight increase with disease and fatality, and administered various
17 controls. They had non-vaccinated. They had an animal that was vaccinated
18 with a low dose of --

19 JUDGE SCHEINER: Is that what we're seeing in figure 5?

20 MR. MCBRIDE: That's figure 5, yes. So yeah, if you look at
21 figure 5, you could see that a number of the individual genes were effective
22 at inducing a -- what they characterize as a protective response compared to
23 the positive controls. In particular the -- what they called CP-4 number 1,
24 which correlates with sequence ID number 6, which encodes the polypeptide
25 of sequence ID number 7. And in fact they identified at least five that were

1 as good or better than the animals that were vaccinated with the low dose
2 live chlamydia psittaci.

3 Subsequently to performing that experiment they also
4 administered the mixture of all 14 clones into bovine, in a bovine infertility
5 model, and found that that mixture was efficacious. Those results are
6 presented in example 8. And then they did some sequence analysis and
7 identified the full length genes that corresponded to the five most protective
8 fragments, synthesized the genes for those full length genes, and used -- they
9 were optimized for expression in mammalian cells. They also expressed the
10 polypeptides corresponding to those and then administered either a mixture
11 of the five genes or a mixture of the five polypeptides in a bovine infertility
12 model as well.

13 So those were the basic examples that they used in the
14 specification to try and justify enablement for the scope of the claims. I
15 guess one thing that I would point out is that the Office has hammered home
16 that the claims -- it's their position that the claims aren't limited to -- aren't
17 enabled for administering a single antigen. But our claims actually are open
18 ended. They're -- use comprising language. So it says it -- comprising
19 sequence ID number 7, so they're not so limited. In addition, we have
20 dependent claims where additional antigens are administered and they
21 haven't -- they haven't addressed what would be sufficient I guess for -- in
22 order to be enabled.

23 JUDGE SCHEINER: Maybe I'm looking at something wrong
24 here, but do we have a 101 here?

1 MR. MCBRIDE: There is a 101 that relates to the fact that the
2 Examiner would like us to recite that the antigen is an isolated antigen or a
3 purified antigen --

4 JUDGE SCHEINER: Oh, okay.

5 MR. MCBRIDE: -- for statutory subject matter purposes.

6 JUDGE SCHEINER: I see.

7 MR. MCBRIDE: And yeah, further to whatever decision
8 is -- you arrive at, we would amend the claims to -- accordingly to address
9 that issue.

10 JUDGE SCHEINER: Okay.

11 MR. MCBRIDE: There's also a 112, second paragraph issue
12 that we intend on addressing after -- after this --

13 JUDGE SCHEINER: Okay.

14 JUDGE PRATS: He's actually answered all the questions I was
15 going to ask anyway, so --

16 JUDGE SCHEINER: Yeah, me too.

17 JUDGE MILLS: Right. I --

18 JUDGE SCHEINER: I don't know if you have anything
19 further, but --

20 JUDGE PRATS: I have nothing.

21 MR. MCBRIDE: Okay, okay.

22 JUDGE SCHEINER: I think we understand the issue.

23 MR. MCBRIDE: Okay, great. Thanks a lot, appreciate it.

24 JUDGE SCHEINER: Okay. I think we probably --

25 Whereupon, at 9:52 a.m., the proceedings were concluded.

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